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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/693,663	10/24/2003	Gene DiPoto	1291.1142101	9623

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EXAMINER	
SWIGER III, JAMES L	
ART UNIT	**PAPER NUMBER**
3775	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/693,663	DIPOTO, GENE	
	Examiner	Art Unit	
	JAMES L. SWIGER	3775	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *25 March 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-32* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-32* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *05 April 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Specification

The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: Applicant has claimed the step of "inclining said access device." It is unclear what applicant means by this term, as no support is found in the specification. It appears that at least applicant's Figs. 39, 45, 46 do not have any significant inclining step.

Appropriate action is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-22 and 31-32 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Applicant has claimed the step of "inclining said access device." It is unclear what applicant means by this term, as no support is found in the specification. It appears that at least applicant's Figs. 39, 45, 46 do not have any significant inclining step.

Appropriate action is required.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-4, 6-12, 14-18 and 23-32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cornwall et al. (US Patent 6,485,518) in view of Davison (US Patent 6,530,926).

Cornwall et al. teaches an intervertebral support and fusion system that allows for transfacet fixation using fasteners (30a and 30b) through one vertebrae to another and where other vertebrae may be adjacent to the surgical site. See Cols. 1 and 2 and also see Col. 3, lines 40-52). It is noted that the method of Cornwall et al. prefers a minimally invasive method (Col. 2, lines 18-21) and teaches that a single-cannula approach is possible in the spirit of a minimally-invasive, percutaneous procedure. It is further noted that Cornwall et al. also teaches the step of positioning at a preferred angle in performing a percutaneous and posteriolateral procedure. Cornwall et al. also teach the delivering of a first fastener to the surgical location, and also advancing the screw from a first vertebra and into a second vertebra.

Cornwall et al. teaches the claimed device except for the specific use of inserting into a patient an access device wherein said access device has a different diameter at a distal end and has two configurations and also the step of inserting multiple fasteners, or the specific step of inclining the access device from a plane that is generally

perpendicular to the spine of the patient. Modification of Cornwall et al to use the device of Davison allows improved access in performing the spinal surgery, yielding more space in the surgical area.

Davison teaches a percutaneous access device and cannula that is inserted into a patient (Fig. 5, 10, and Col. 2, lines 58-63), and wherein the access device has a first and second configuration (Col. 3, lines 3-39) and, with regards to claims 8-13 and 23, multiple fasteners can be inserted through the cannula to secure vertebrae. Davison teaches that multiple fasteners may be inserted (see Col. 13, lines 15-25, and Abstract). Additionally, in use of the device, the screws 30a and 30b are slightly angled to perform transfacet fixation.

Additionally, a substantially perpendicular plane with respect to the spine, denoted by the dotted line in Fig. 1 of Cornwall et al. must be crossed by the minimally-invasive cannula to complete the procedure for both screws. The plane represented in the drawing is a visual landmark and as noted previously, the cannula is moved to insert a bone fastener with respect to this point. Thus, Davis teaches the step, of the device moving from a plane generally perpendicular to the spine of the patient at an established angle. It is an “angled approach.” The cannula may be slightly (i.e. substantially perpendicular) angled to complete the procedure and deliver the screws accordingly.

With regards to step of specifically “inclining” it is noted that this is an obvious step modification in view of the following reasoning. Though applicant has not provided any specifics of inclining, it is noted that as surgeon is inserting the fasteners into the

spine, he or she is utilizing the elongated and proximal portion of the access device. As Cornwall is designed to be used with minimally invasive or percutaneous procedures, an access device such as taught by Davison provides a means to perform percutaneous surgery. However, because it is a percutaneous procedure, the size of an incision is of limited size. And because the incision is limited, there may not be enough room via the access device to access the entire surgical area (in this case, the spine) without moving the device. Thus with Cornwall in view of Davison, it would be obvious to *incline* the device with respect to a perpendicularly defined reference point, as this would allow the surgeon to adequately have a proper angle or proper space required to insert the fasteners into the spine.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to perform the method of Cornwall et al. having/using the access device as taught by Davison to have improved access to the spinal area with a first and second configuration at an end for adjoining and securing vertebrae and also for inserting multiple screws in the vertebral area including the step of inclining.

Claims 5 and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of Cornwall et al. ‘518 and Davison '926 as applied to claims 1 and 8, respectively above, and further in view of Neubardt (US Patent 5,196,015). The combination of Cornwall et al. ‘518 and Davison '926 disclose the claimed method except for the step of scoring the surgical location prior to delivering the fastener through the bone. Neubardt discloses an indirect scoring of the area that is performed

by placing the tool to the area and verifying the mark of the tool tip by indicia located on the tool shaft. (Col. 5, lines 10-16). In this way the location is marked before the fastener or securing device is delivered. It would have been obvious to one having ordinary skill in the art at the time the invention was made to incorporate into the method of the combination of Cornwall et al. '518 and Davison '926 with the step of scoring and marking the area of interest for securing the fasteners in view of Neubardt to provide accurate fixation in a minimal access procedure.

Claims 19-20 and 21-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of Cornwall et al. '518 and Davison '926.
The combination of Cornwall et al. '518 and Davison '926 discloses the claimed invention except for a "generally perpendicular angle being between 10 and 45 degrees, or at least less than 60." It would have been obvious to one having ordinary skill in the art at the time the invention was made to make a range of angle being between 10 and 45 degrees, or at least less than 60, since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art, especially for access the spine posteriorly through a device. In re Boesch, 617 F.2d 272, 205 USPQ 215 (CCPA 1980).

Response to Arguments

The FINALITY of the Final office action dated 1/27/2009 is hereby WITHDRAWN.

With regards to applicant's arguments, filed in the pre-appeal brief on 3/25/2009, they have been fully considered but are not entirely persuasive. The examiner has added a section to the enclosed action to "provide an explanation as to non-

persuasiveness" in regards to the arguments submitted on 11/4/2008. Applicant further noted that examiner must give pending claims "their broadest reasonable interpretation consistent with the specification." However, as the examiner has pointed out in the beginning of this action, the applicant has failed to provide an adequate specification to enable one of ordinary skill in the art to understand what is being claimed.

Particularly, applicant has argued the step of “inclining.” The examiner continues to disagree with applicant's arguments, particularly, that the step of "inclining" is an obvious step modification as it is inherently necessary during a surgical procedure due to the nature of the surgery and the tools utilized. Further, as Cornwall discloses essentially the entire procedure, it still requires that the area be accessed via percutaneous methods. Implied percutaneous methods aside in Cornwall, Davison discloses at least additional, if not improved percutaneous methods to use.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JAMES L. SWIGER whose telephone number is (571)272-5557. The examiner can normally be reached on M-F 9-530.

If attempts to reach the examiner by telephone are unsuccessful, the examiner’s supervisor, Thomas Barrett can be reached on 571-272-4746. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/JAMES L. SWIGER/
Examiner, Art Unit 3775

/Thomas C. Barrett/
Supervisory Patent Examiner, Art Unit 3775